

JUL 7 - 2005

Quantum Orthopedics, Inc.  
Premarket Notification – Quantum Vertebral Body Replacement

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**510(k) Summary**  
**Quantum Vertebral Body Replacement**

**510(k) Number K050449**

***Manufacturer Identification***

**Submitted by:**

Quantum Orthopedics, Inc.  
2744 Loker Ave. W., Suite 100  
Carlsbad, CA 92008  
760-607-0121

**Contact Information:**

Jason Blain  
Chief Technology Officer  
Quantum Orthopedics, Inc.  
2744 Loker Ave. W., Suite 100  
Carlsbad, CA 92008  
760-607-0121  
jblain@quantumorthopedics.com

**Date Prepared:**

May 13, 2005

***Device Identification***

**Proprietary Name:**

Quantum Vertebral Body Replacement

**Common Name:**

Vertebral Body Replacement

**Classification Name:**

Spinal Vertebral Body Replacement

***Device Description***

The Quantum Vertebral Body Replacement is a generally box-shaped device with various holes located throughout its geometry. The exterior surface of the device has teeth to help keep the device from migrating once placed in its desired location. It is available in a multitude of sizes to suit the individual pathology and anatomic condition of the patient. The device may be made from titanium or polyetheretherketone (PEEK).

***Intended Use of the Device***

The Quantum Vertebral Body Replacement is intended for use in the thoracic and/or thoracolumbar spine (T1-L5) to replace a collapsed, damaged, or unstable vertebral body resected or excised (i.e., partial or total vertebrectomy procedures) due to tumor or trauma (i.e., fracture).

This device is intended to be used with supplemental spinal fixation systems that have been cleared for use in the thoracic and/or lumbar spine (i.e., posterior pedicle screw and

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rod systems, anterior plate systems, and anterior screw and rod systems). The interior of the spacer can be packed with allograft or autograft.

***Substantial Equivalence***

The Quantum Vertebral Body Replacement was shown to be substantially equivalent to Sustain Radiolucent Spacer (Globus Medical, Inc., K040284), Cadence<sup>TM</sup> and Traxis<sup>TM</sup> (Spinal Concepts, K033517), PEEK Tetris<sup>TM</sup> (Signus Medical LLC, K031757 and K041888), STALIF<sup>TM</sup> TT (Surgicraft, K041617), and SynMesh (Synthes, K003275).

***Performance Data***

Mechanical testing indicates that the Quantum Vertebral Body Replacement is capable of performing in accordance with its intended use.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

JUL 7 - 2005

Mr. Jason Blain  
Chief Technology Officer  
Quantum Orthopedics  
2744 Loker Avenue West, Suite 100  
Carlsbad, California 92008

Re: K050449

Trade/Device Name: Quantum Vertebral Body Replacement  
Regulation Number: 21 CFR 888.3060  
Regulation Name: Spinal intervertebral body fixation orthosis  
Regulatory Class: II  
Product Code: MQP  
Dated: May 13, 2005  
Received: May 16, 2005

Dear Mr. Blain:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

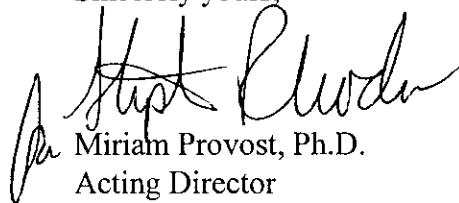
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 – Mr. Jason Blain

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Miriam Provost", is written over the typed name.

Miriam Provost, Ph.D.  
Acting Director  
Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known):

Device Name: Quantum Vertebral Body Replacement

### Indications For Use:

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This device is intended to be used with supplemental spinal fixation systems that have been cleared for use in the thoracic and/or lumbar spine (i.e., posterior pedicle screw and rod systems, anterior plate systems, and anterior screw and rod systems). The interior of the spacer can be packed with allograft or autograft.

Prescription Use   X    
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

Division of General, Restorative,  
and Neurological Devices

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